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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,718	08/07/2001	Lars S. Nielsen	NIELSEN=2D	9477

7590 03/11/2003

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/11/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/922,718

Applicant(s)
Nielsen et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 7, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. Claims 1-69 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-96. Claims 1-9 are drawn to a method for better understanding at least one of four variables drawn to tumors by determining the level of four markers, classified in Class 435, subclasses 4, 7.1. It is noted that the number of groups have been determined by Factorial analysis wherein the at least one of four variables equals $4!$ which equals 24 and whereby determining the level of each marker for each of the groups is considered a distinct invention, thus 4 times 24 equals 96 groups. Applicant is required to elect a single invention, that is, a single marker and one or more specifically identified variables. Claims 27-33, 56-69 will be examined as they are drawn to the elected invention. Claims 35, 36, 40, 41, 42, 51 will be examined as they are drawn to the elected invention.

In addition it is noted that in addition to the 96 distinct groups claimed in claim 1 as disclosed above, claim 1 has been determined to be a linking claim as

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drawn to tumor type. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 and 36 (if drawn to the elected invention). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Upon election of a single group as required above, Applicant must elect a single group from those set forth below.

Group 97. Claims 1, 10 are drawn to a method as elected above for better understanding breast tumor, classified in Class 435, subclasses 4, 7.1. Claims 16-24, 27-34, 36 (if drawn to the elected invention) 39 will be examined as they are drawn to the elected invention.

Group 98. Claims 1, 11 are drawn to a method as elected above for better understanding gastric tumor, classified in Class 435, subclasses 4, 7.1. Claim 16-21, 23-24, 27-34, 36 (if drawn to the elected invention), 39 will be examined as they are drawn to the elected invention.

Group 99. Claims 1, 12 are drawn to a method as elected above for the

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better understanding of colon tumor, classified in Class 435, subclasses 4, 7.1. Claim 16-21, 23-25, 27-34, 36 (if drawn to the elected invention), 39, 51 (as it is drawn to the elected invention), 52 will be examined as they are drawn to the elected invention.

Group 100. Claims 1, 13 are drawn to a method as elected above for better understanding of lung tumor, classified in Class 435, subclasses 4, 7.1. Claim 16-21, 23-24, 27-34, 36 (if drawn to the elected invention), 39 will be examined as they are drawn to the elected invention.

Group 101. Claims 1, 14 are drawn to a method as elected above for the better understanding of ovarian tumor, classified in Class 435, subclasses 4, 7.1. Claim 14, 17-24, 27-34, 36 (if drawn to the elected invention), 39 will be examined as they are drawn to the elected invention.

Group 102. Claims 1, 17, 21, 22 are drawn to a method as elected above for the better understanding of pancreatic tumor, classified in Class 435, subclasses 4, 7.1. Claim 16-21, 23-24, 27-33 will be examined as they are drawn to the elected invention.

Group 103. Claims 1, 17, 21, 22 are drawn to a method as elected above for the better understanding of urinary tract tumor, classified in Class 435, subclasses 4, 7.1. Claim 16-21, 23-24, 27-34, 36 (if drawn to the elected invention), 39 will be examined as they are drawn to the elected invention.

Group 104. Claims 1, 17, 21, 22 are drawn to a method as elected above for the better understanding of colorectal tumor, classified in Class 435, subclasses 4, 7.1. Claim 18-21, 23-24, 27-34, 36 (if drawn to the elected invention), 39 will be examined as they are drawn to the elected invention.

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Group 105. Claims 1, 34, 36 (if drawn to the elected invention) 39 are drawn to a method as elected above for the better understanding of gynecological carcinomas other than ovarian, classified in Class 435, subclasses 4, 7.1.

Group 106. Claims 1, 34, 36 (if drawn to the elected invention), 39 are drawn to a method as elected above for the better understanding of brain tumors, classified in Class 435, subclasses 4, 7.1.

Group 107. Claims 1, 34, 36 (if drawn to the elected invention), 39 are drawn to a method as elected above for the better understanding of sarcomas, classified in Class 435, subclasses 4, 7.1.

Group 108. Claims 1, 34, 36 (if drawn to the elected invention), 39 are drawn to a method as elected above for the better understanding of haematological malignancy, classified in Class 435, subclasses 4, 7.1.

Group 109. Claims 1, 34, 36 (if drawn to the elected invention), 39 are drawn to a method as elected above for the better understanding of skin cancers, classified in Class 435, subclasses 4, 7.1.

Group 110. Claims 36-38, 45 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 DNA abundance, classified in Class 435, subclass 6.

Group 111. Claims 36-38, 45 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 RNA abundance, classified in Class 435, subclass 6.

Group 111a. Claims 36-38, 45, 53 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 protein abundance, classified in Class 435, subclass 6.

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Group 112. Claims 36-38, 45 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 RNA and PAI-1 DNA abundance, classified in Class 435, subclass 6.

Group 113. Claims 36-38, 45 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 RNA and PAI-1 protein abundance, classified in Class 435, subclasses 4, 6, 7.1.

Group 114. Claims 36-38, 45 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 DNA abundance and PAI-1 protein abundance, classified in Class 435, subclasses 4, 6, 7.1.

Group 115. Claims 36-38, 45 are drawn to a method of detecting the presence of a malignant tumor comprising assaying PAI-1 RNA, DNA, protein abundance, classified in Class 435, subclasses 4, 6, 7.1.

Group 116. Claims 36-38, 45 are drawn to a method of detecting the presence of a progression of malignant tumor comprising assaying PAI-1 DNA abundance, classified in Class 435, subclass 6.

Group 117. Claims 36-38, 45 are drawn to a method of detecting the presence of a progression of malignant tumor comprising assaying PAI-1 RNA abundance, classified in Class 435, subclass 6.

Group 118. Claims 36-38, 45 are drawn to a method of detecting the presence of a progression of malignant tumor comprising assaying PAI-1 RNA and PAI-1 DNA abundance, classified in Class 435, subclass 6.

Group 119. Claims 36-38, 45 are drawn to a method of detecting the presence of a progression of malignant tumor comprising assaying PAI-1 RNA and PAI-1 protein abundance, classified in Class 435, subclasses 4, 6, 7.1.

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Group 120. Claims 36-38, 45 are drawn to a method of detecting the presence of a progression of malignant tumor comprising assaying PAI-1 DNA abundance and PAI-1 protein abundance, classified in Class 435, subclasses 4, 6, 7.1.

Group 121. Claims 36-38, 45 are drawn to a method of detecting the presence of a progression of malignant tumor comprising assaying PAI-1 RNA, DNA, protein abundance, classified in Class 435, subclasses 4, 6, 7.1.

In addition it is noted that in addition to the 13 distinct groups claimed in claim 36, but not claimed in claim 1 as disclosed above, claims 36 and 53 have been determined to be a linking claim as drawn to tumor type. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 and 36 (if drawn to the elected invention). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Upon election of a single group as required above, Applicant must elect a single group from those set forth below.

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Group 122 and 123. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is mammary carcinoma, classified in Class 435, subclass 4+ . Claims 45 and 55 will be examined as they are is drawn to the elected invention.

Group 124 and 125. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is urological carcinoma, classified in Class 435, subclass 4+ . Claim 45 and 55 will be examined as they are drawn to the elected invention.

Group 125 and 126. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is gynaecological carcinoma, classified in Class 435, subclass 4+ . Claim 45 and 55 will be examined as they are drawn to the elected invention.

Group 127 and 128. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is non-small cell lung tumor, classified in Class 435, subclass 4+ . Claim 45 and 55 will be examined as they are drawn to the elected invention.

Group 129 and 130. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is gastrointestinal cancers, classified in Class 435, subclass 4+ .

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Claim 45 and 55 will be examined as they are drawn to the elected invention.

Group 131 and 132. Claims 36 and 39 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is brain tumors, classified in Class 435, subclass 4+ . Claim 45 will be examined as it is drawn to the elected invention.

Group 133 and 134. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is sarcomas, classified in Class 435, subclass 4+ . Claim 45 and 55 will be examined as they are drawn to the elected invention.

Group 135 and 136. Claims 36, 39, 53 (as drawn to the elected invention), 54 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is haematological malignancy, classified in Class 435, subclass 4+ . Claim 45 and 55 will be examined as they are drawn to the elected invention.

Group 137 and 138. Claims 36 and 39 are drawn to a method as elected for detecting the presence or progression of a malignant tumor, each of which is a distinct invention, wherein the malignant tumor is skin cancers, classified in Class 435, subclass 4+ . Claim 45 will be examined as it is drawn to the elected invention.

Group 139. Claim 43 is drawn to a method of predicting the prognosis of an individual having a malignant tumor, classified in Class 435, subclasses, 4 and 7.1.

Group 140. Claim 43 is drawn to a method of predicting the prognosis of an individual suspected of having or a malignant tumor, classified in Class 435,

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subclasses, 4 and 7.1.

Group 141. Claim 44-49 is drawn to a method of detecting uPA:PAI-1 complex, classified in Class 435, subclasses, 4 and 7.1.

Group 142. Claim 49-50 is drawn to a method of detecting uPA:PAI-1 complex and total uPA in a sample, classified in Class 435, subclasses, 4 and 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions III-VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. The claimed Groups are further subject to election of a single disclosed species..

The species elections required, as appropriate, for the elected invention are

(A) Samples which require different types of assays and different methods wherein the samples are frozen tumor tissue, unfixed tumor tissue, extracts of tumor tissue, sample of body fluid, tumor tissue, normal cells, malignant tissue

(B) Assays with different methods wherein the assays are immunoassay, activity assay,

(C) Monoclonal antibodies with different structures and functions wherein the antibodies are HT-1080, Clone 1, 2, 3, 4.

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6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from

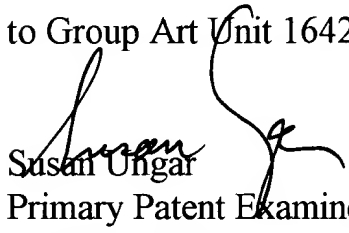
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the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
March 6, 2003